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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,705	06/08/2001	Xianqiang Li	26757-704	1050

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/26/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,705

Applicant(s)

LI, XIANQIANG

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Specification

The amendment to the specification and replacement of a new abstract obviates the objection to the disclosure.

Status of Claims

Claims 1-19 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action.

Response to Arguments

Applicants argue that pages 41-45 describe ample examples of libraries of compounds or agents that are used in the

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screening for transcription factor modulators. Applicants admit that the illustration relates to an agent PMA (phorbol ester) which was found to modulate transcription factor(tf) activities in different cancer cells.

In response, the claims do not recite for libraries of modulators or agents. Rather, a library of double stranded (ds) nucleic acid probes. It is not clear whether these nucleic acid probes are the agents or the transcription factors. Furthermore, the cited sections provide only a list of what could possibly be the modulating agents that can possibly be used in the method. There is no evidence of record or reasonable assurance in the disclosure that the single illustrated PMA agent can be extrapolated to the myriads of agents, as claimed. As stated in the last office action, the methodology does not present any experiments as to how the library, if any, modulators are made. Let alone, how the screening is achieved for said modulators. The Examples present only results of an alleged experiment. A detail method of the experiments such as the conditions, the library and the materials for the methods are not positively recited. Absent any description and direction, the complex determination of the numerous different variables of the invention is not adequately described. As applicants recognize, each tf probe has binding specificity for a single transcription

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factor or family of transcription factors. Note further the numerous attempts by applicants to employ several methods for the isolation of the tf-probe complex. Some of which failed to provide a sufficient yield of probe-transcription factor complexes from the sample. For example, applicants attempted to isolate probe-transcription factor complexes by performing an ammonia precipitation. Applicants also attempted to isolate probe-transcription factor complexes by passing the sample through a nitrocellulose filter, the filter serving to immobilize proteins while allowing DNA that is not bound to protein to pass through the filter. Unfortunately, neither of these approaches provided a satisfactory yield of complexes for further characterization of the isolated probes. Applicant also attempted to isolate probe-transcription factor complexes by using acrylamide gel electrophoresis. Unfortunately, this approach also did not provide a satisfactory yield of complexes. After several attempts Applicant successfully isolated probe-transcription factor complexes from the sample using agarose gel electrophoresis. [The separation method is but one of the numerous undefined variables of the claimed]. Thus, the generalized statements in the specification are not an adequate written description of the invention. Accordingly, the alleged

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illustration of a single agent is so specific that would lead one skilled in the art to the specifically embodied example.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

A). Applicants argue that claim 1 has been amended by incorporating the language "comparing...the test sample with a control....." thus, obviating the rejection.

In response, the newly incorporated language does not obviate this rejection. The claims do not recite for a library of modulators that needs to be screened to identify the tf modulators. Cf. with pages 41-45, cited by applicant above, which recites screening a library of modulators to identify said modulators that affect the activated tf.

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B). Applicants argue that one of ordinary skill in the art would understand if 1% or more of the nucleic acid probes (e.g., 2 probes out of 100 probes in the library) contains the recognition sequences greater than 35 base pair in length, it is within the scope of the open-ended range "at least 1%".

In reply, if this is so, then the recognition sequences could be the entire ds nucleic acid probes. If it is greater than e.g., 35 base pair, which library will contain the at least 1%? Thus, the language is confusing as to the limitation of said percent amount.

C). In view of the amendments to claims 8-9 the rejection no longer applies.

D). Applicants argue that the open-ended range is not indefinite. However, it is not clear whether each of the library of the ds nucleic acid probes contain each at least 5 recognition sequences. In a ds probes is the at least 5 recognition sequences contain in one strand or both strands?

E). The amendment to claim 17 obviates the rejection.

The following rejections apply to the newly amended claims:

1. Claim 1 is indefinite as to the "nucleic acid probes" it is not clear whether this is the same as the tf factor probes. It is not clear as to which the conjunction "and"

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refers to. It is further not clear as to the means or steps by which a recognition sequence is **predetermined**. As stated in the above rejection A) the claim is confusing as appearing to determine or detect nucleic acid probes complexing with activated tf. It is not clear whether the comparing step is with the complex hybrid probes as recited in the preceding steps. Furthermore, the comparative step simply recites that the agent modulates a tf and but not screened (since no library of modulators is recited in the preceding steps).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al (US 6,066,452) for reasons of record.

Response to Arguments

It is argued that the claims as amended specifies a method for screening a tf modulator by comparing multiple different tf in cells treated with or without any of the different agents. Specifically, the presence of the multiple different transcription factors in the cell samples is detected by using a library of nucleic probes each of which comprises a predetermined, known recognition sequence to identify tf in the sample that are known to bind to the recognition sequences. Weissman is argued to describe nucleic acid probes with randomized sequences to fish out tf that can bind to any of the randomized DNA sequences. It is further argued that Weissman does not teach or suggest using a library of probes each of which comprises a predetermined known recognition sequence to identify tf in the sample that are known to bind to the recognition sequences.

In response, a random peptide sequence does not mean it is not a known sequence. Rather, it is a known sequence with part of the known sequence being varied. It would be within the ordinary skill in the art to pick or choose a known sequence for such determination. Note further that applicants' arguments appear not to be commensurate in scope with the claims which recites screening for a modulator.

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Double Patenting

The double patenting rejection of claims 1-19 over the copending Application No. 09/877,243('243 application) or copending application No. 09/947,274('274 application) has been obviated with the Terminal disclaimer of record.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

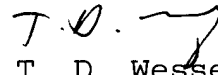
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 25, 2003